

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Donald J. Larnard, et al

Application No.: Not Yet Assigned

Filing Date: Herein

Entitled: EXPANDABLE DEVICE FOR  
THERMAL THERAPY

Docket No.: 22521-2CON

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT

Mail Stop Patent Application  
Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22312-1450

Dear Sir:

It is desired to cite for the record in this application the cited articles, United States and foreign patents listed on the attached copy of Form PTO/SB/08A. The paragraph(s) marked below are applicable to this Information Disclosure Statement.

The attached Form PTO/SB/08A provides a listing of information which may be relevant to the subject application. This Information Disclosure Statement is not intended as a representation that better art is not available, or that the information provided is prior art.

In accordance with M.P.E.P. § 609, copies of the cited references are not provided herewith because (1) the information was previously cited and/or submitted in connection with parent application no. 09/971,015 which is relied on for an earlier filing date under 35 U.S.C. 120; and (2) the IDS submitted in the earlier application complies with 37 CFR 1.98(a)-(c).

☒ (1) The enclosed Information Disclosure Statement is being filed within three months of the filing date or within three months of the date of entry of the national stage of the above-identified application. Accordingly, Applicant(s) believes that no fee or certification is required.

☐ (1a) The enclosed Information Disclosure Statement is being filed before the mailing of a first Office action on the merits under 37 C.F.R. §1.97(b)(3); or before the mailing of a first Office action after the filing of a request for continued examination under §1.114. Accordingly, Applicant(s) believes that no fee or certification is required.

☐ (1b) Pursuant to 37 C.F.R. §1.97(c), the enclosed Information Disclosure Statement is being filed before the mailing date of a final action or a notice of allowance and is accompanied by the fee set forth in § 1.17(p).

☐ (2) Pursuant to 37 C.F.R. § 1.97(d), Applicant states that the issue fee has not been paid and that a certification under 37 C.F.R. §1.97(e) is provided herein, along with the fee of \$180.00 required under 37 C.F.R. §1.17(p).

CERTIFICATION UNDER 37 C.F.R. §1.97(e) (1)

☐ (3) The undersigned hereby certifies that each item of information contained in the attached Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application mailed not more than three months prior to the filing of this statement.

CERTIFICATION UNDER 37 C.F.R. §1.97(e) (2)

☐ (4) The undersigned hereby certifies that no item of information contained in the attached Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, after making reasonable inquiry, was known to any individual having a duty of disclosure as set forth in 37 C.F.R. §1.56(c) more than three months prior to the filing of this statement.

The filing of this Information Disclosure Statement is not representation by the undersigned as to the personal knowledge of the contents of every word or phrase of the material enclosed or that reliance on other suitably trained professionals has not been made.

If a search report of a searching agency is enclosed identifying the nature of the relevance of each document, such a designation is deemed to satisfy Rule 98(a) (3) even if in a foreign language, since the few terms of relevance therein are deemed of universal cognizance. However, Applicant does not necessarily adopt the position reflected by that report.

It is respectfully requested that the cited references be considered by the Examiner and that a copy of the enclosed Form PTO/SB/08A be initialed and returned to us indicating that such information has been considered.

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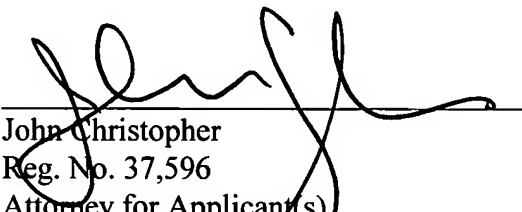
Atty. Docket No. 22521-2CON

The Commissioner is hereby authorized to credit overpayments or charge payment of any additional fees associated with this communication to Deposit Account No. 502104.

Respectfully submitted,

Dated: February 20, 2004

By:



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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	Not Yet Assigned
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				First Named Inventor	Donald J. Larnard, et al.
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Examiner Name	Not Yet Assigned				
Sheet	1	of	5	Attorney Docket Number	22521-2CON
<b>U.S. PATENT DOCUMENTS</b>					
Examiner Initials *	Cite No. <sup>1</sup>	Document Number  Number- Kind Code <sup>2</sup> <i>(if known)</i>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-2,190,384	02/13/1940	Newman	
		US-3,170,465	02/23/1965	Henney, et al.	
		US-3,174,841	03/23/1965	Seaman	
		US-3,220,414	11/30/1965	Johnston	
		US-3,504,674	04/07/1970	Swenson, et al.	
		US-3,736,936	06/05/1973	Basiulis, et al.	
		US-3,776,241	12/04/1973	Magilton, et al.	
		US-3,848,607	11/19/1974	St. Clair	
		US-3,897,790	08/05/1975	Magilton, et al.	
		US-4,010,795	03/08/1977	K. Steinberg	
		US-4,207,897	06/17/1980	Lloyd, et al.	
		US-4,719,919	01/19/1988	Marchosky, et al.	
		US-4,781,193	11/01/1988	Pagden	
		US-4,860,744	08/29/1989	Johnson, et al.	
		US-4,946,460	08/07/1990	Merry, et al.	
		US-4,989,601	02/05/1991	Marchosky, et al.	
		US-5,108,407	04/28/1992	G.K. Geremia, et al.	
		US-5,209,227	05/11/1993	Deutsch	
		US-5,207,674	05/04/1993	Hamilton	
		US-5,261,399	11/16/1993	Klatz, et al.	
		US-5,304,214	04/19/1994	DeFord, et al.	
		US-5,334,181	08/02/1994	Rubinsky, et al.	
		US-5,380,319	01/10/1995	Saito, et al.	
		US-5,417,686	05/23/1995	Peterson, et al.	
		US-5,429,582	07/04/1995	Williams	
		US-5,474,533	12/12/1995	Ward, et al.	
		US-5,520,682	05/28/1996	Baust, et al.	
		US-5,609,620	03/11/1997	P.O. Daily	
		US-5,531,776	07/02/1996	Ward, et al.	
		US-5,540,711	07/30/1996	Kieturakis, et al.	
		US-5,549,559	08/27/1996	Eshel	
		US-5,591,162	01/07/1997	Fletcher, et al.	
		US-5,607,443	03/04/1997	Kieturakis, et al.	
		US-5,611,767	03/18/1997	Williams	
		US-5,624,392	04/29/1997	Sabb	
		US-5,643,207	07/01/1997	Rise	
		US-5,645,528	07/08/1997	Thorne	
		US-5,713,923	02/03/1998	Ward, et al.	
		US-5,716,353	02/10/1998	Matsuura, et al.	
		US-5,716,386	02/10/1998	Ward, et al.	

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		US-5,718,584	02/17/1998	Wong	
		US-5,718,684	02/17/1998	Gupta	
		US-5,730,756	03/24/1998	Kieturakis, et al.	
		US-5,735,817	04/07/1998	Shantha	
		US-5,772,680	06/30/1998	Kieturakis, et al.	
		US-5,814,014	09/29/1998	Elsberry, et al.	
		US-5,817,123	10/06/1998	Kieturakis, et al.	
		US-5,843,075	12/01/1998	Taylor	
		US-5,871,498	02/16/1999	Jervis, et al.	
		US-5,891,134	04/06/1999	C. Goble, et al.	
		US-5,899,898	05/04/1999	Arless, et al.	
		US-5,913,885	06/22/1999	Klatz, et al.	
		US-5,916,212	06/29/1999	Baust, et al.	
		US-5,916,242	06/29/1999	Schwartz	
		US-5,928,203	07/27/1999	Davey, et al.	
		US-5,951,512	09/14/1999	Dalton	
		US-5,954,714	09/21/1999	Saadat, et al.	
		US-5,957,963	09/28/1999	Dobak, III	
		US-5,972,714	10/26/1999	Keep, et al.	
		US-5,976,109	11/02/1999	Heruth	
		US-6,004,337	12/21/1999	Kieturakis, et al.	
		US-6,015,382	01/18/2000	Zwart, et al.	
		US-6,015,421	01/18/2000	Echeverry, et al.	
		US-6,017,324	01/25/2000	Tu, et al.	
		US-6,030,412	02/29/2000	Klatz, et al.	
		US-6,042,579	03/28/2000	Elsberry, et al.	
		US-6,045,532	04/04/2000	Eggers, et al.	
		US-6,051,019	04/18/2000	Dobak, III	
		US-6,053,913	04/25/2000	Tu, et al.	
		US-6,073,051	06/06/2000	Sharkey, et al.	
		US-6,074,412	06/13/2000	Mikus, et al.	
		US-6,083,148	07/04/2000	Williams	
		US-6,090,132	07/18/2000	Fox	
		US-6,096,068	08/01/2000	Dobak, III, et al.	
		US-6,106,518	08/22/2000	Wittenberger, et al.	
		US-6,113,593	09/05/2000	Tu, et al.	
		US-6,117,128	09/12/2000	Gregory	
		US-6,122,549	09/19/2000	Sharkey, et al.	
		US-6,123,718	09/26/2000	Tu, et al.	
		US-6,126,680	10/03/2000	Wass	
		US-6,126,684	10/03/2000	Gobin, et al.	
		US-6,129,736	10/10/2000	Jervis, et al.	
		US-6,132,415	10/17/2000	Finch, et al.	
		US-6,146,411	11/14/2000	Noda, et al.	

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		US-6,149,677	11/21/2000	Dobak, III	
		US-6,152,920	11/28/2000	Thompson, et al.	
		US-6,156,057	12/05/2000	Fox	
		US-6,168,608 B1	01/02/2001	Echeverry, et al.	
		US-6,179,831 B1	01/30/2001	Blweis	
		US-6,183,501 B1	02/06/2001	Latham	
		US-6,224,624 B1	05/01/2001	Lasheras, et al.	
		US-6,238,428 B1	05/29/2001	Wemeth, et al.	
		US-6,248,126 B1	06/19/2001	Lesser, et al.	
		US-6,251,129 B1	06/26/2001	Dobak, III et al.	
		US-6,251,130 B1	06/26/2001	Dobak, III et al.	
		US-6,322,559 B1	11/27/2001	J.S. Daulton, et al.	
		US-6,383,210 B1	05/07/2002	M. Magers, et al.	

<b>FOREIGN PATENT DOCUMENTS</b>						
Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD- YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
		PCT WO 99/34758	07/15/1999			
		PCT WO 96/03943	02/15/1996			
		PCT WO 00/07507	02/17/2000			
		PCT WO 00/59419	10/12/2000			
		PCT WO 01/17471	03/15/2001			
		PCT WO 01/76517	10/18/2001			
		EP 0132276 B1	01/30/1985			
		EP 0382787 B1	08/22/1990			
		EP 0586567 B1	03/16/1994			
		DE 19521166 C2	12/12/1996			X
		JP 5-500858	12/23/1992			X
		JP 5-505399	03/18/1993			X
		JP 11-51900	09/12/2000			X
		JP 11-170076	11/28/2000			X
		JP 2000/126973	12/12/2000			X
		JP 11-290530	04/17/2001			X
		RU SU211736	11/19/1968			X
		RU SU293381	01/02/1969			X
		RU SU432907	07/18/1972			X
		RU SU639557	05/15/1975			X
		RU SU833266	11/20/1978			X
		RU SU1138152A	09/22/1983			X
		RU SU1544422A1	05/24/1988			X
		RU SU1745238A1	07/13/1990			X
		RU SU1787026A3	08/09/1990			X
		RU 2100989C1	01/10/1998			X
Examiner Signature			Date Considered			

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP901.04. <sup>3</sup>

<sup>4</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>5</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>7</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet	4	of	5	Attorney Docket Number	22521-2CON

<b>OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS</b>			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Fay, "Early Experiences with Local and Generalized Reirgeration of the Human Brain", Temple Fay, M.D., Pgs. 239-260	
		Perov, et al., "Design of Thermodes for Cooling Sites of Cerebral Hemisphere Cortex in Chronic Tests", Sechenov Physiology Journal of the USSR, No. 7, 1983, Methods of Physiological Investigations, 5 pgs.	
		Connolly, et al., "The protective of hypothermia in cerebral ischemia: Experimental and clinical application by selective brain cooling in the human", Dept. of Surgery, Stanford Universtiy School of Medicine, Vol. 52, No. 1, July 1962, pgs. 15-24.	
		Kindt, et al., "Regional Hypothermia Produced by Cooling the Blood within the Intact Artery", Surgical Forum, 1966, 17: pgs. 406-7.	
		Locke, et al., "Profound Selective Arterial Cooling of Brain without Pump or Oxygenator", Surgical Forum, 1965, 16: pgs. 421-2.	
		Negrin, "An Instrument to Obtain Local Hypothermia of the Brain or Spinal Cord", International Surgery, August 1970, Vol. 54, No. 2, pgs. 93-106.	
Examiner Signature		Date Considered	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached  
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<b>Sheet</b>	5	of	5	<b>Attorney Docket Number</b>	22521-2CON

<b>OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS</b>			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Mursky, "On the Use of Complex (Cranial Cerebral and General) Hypothermia in Experiments", Brain Hypothermia, 1965, 4 pgs.	
		Shilo, et al., "Delivery/Dialysis Cannula for Local Superfusion of Brain Structures at Cranial Cerebral Hypothermia", Collection of Scientific Works, 1988, 3 pgs.	
		Rybakov, "Method of Intra-Ventricle Hypothermia of Brain", 3 pgs.	
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